

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION

v.

This Document Relates To:

Tallman, 1:13-cv-10349; *Landon*, 1:13-cv-10352; *Shrock*, 1:13-cv-10353; *Rethlake*, 1:13-cv-10354; *Oblinger*, 1:13-cv-10355; *Wyres*, 1:13-cv-10356; *Geisler*, 1:13-cv-10357; *Ginther*, 1:13-cv-10363; *Klemm*, 1:13-cv-10371; *Pavlekovich*, 1:13-cv-10373; *Copsey*, 1:13-cv-10503; *Tolbert*, 1:13-cv-10507; *Huff*, 1:13-cv-10511; *Craig*, 1:14-cv-12367; *Bostic*, 1:14-cv-12371; *Smith*, 1:14-cv-12531; *Lenhart*, 1:14-cv-12561; *Polk*, 1:14-cv-12573; *Pringle*, 1:14-cv-12574; *Elliott*, 1:14-cv-12597; *Alcozar*, 1:14-cv-12598; *Durben*, 1:14-cv-12599; *Frick*, 1:14-cv-12611; *Holden*, 1:14-cv-12616; *Wegner*, 1:14-cv-12619; *Wolfe*, 1:14-cv-12622; *Glon-Ullery*, 1:14-cv-12838; *Barnes*, 1:14-cv-12864; *Briggs*, 1:14-cv-12869; *Browning*, 1:14-cv-12872; *Hunt*, 1:14-cv-12875; *Lay*, 1:14-cv-12909; *Haas*, 1:14-cv-12912; *Konanz*, 1:14-cv-12913; *McClure*, 1:14-cv-12914; *Owen*, 1:14-cv-13006; *Pinneyi*, 1:14-cv-13010; *Robinson*, 1:14-cv-13011; *Pedler*, 1:14-cv-13012; *Probst*, 1:14-cv-13014; *Shafer*, 1:14-cv-13015; *Pletcher*, 1:14-cv-13016; *Soli*, 1:14-cv-13017; *Koziatek*, 1:14-cv-13018; *Jones*, 1:14-cv-13021; *McQueen*, 1:14-cv-13025; *Cookson*, 1:14-cv-13081; *Allen*, 1:14-cv-13082; *Garl*, 1:14-cv-13083; *Copp*, 1:14-cv-13084; *Pritchard*, 1:14-cv-13157; *Lawson*, 1:14-cv-13158; *Cobb*, 1:14-cv-13200; *Greenwood*, 1:14-cv-13202; *Grice*, 1:14-cv-13204; *Holt*, 1:14-cv-13206; *Hurst*, 1:14-cv-13207; *Ivory*, 1:14-cv-13209; *Sims*, 1:14-cv-13212; *Sinn*, 1:14-cv-13213; *Stokes*, 1:14-cv-13217; *VanSchoiack*, 1:14-cv-13218; *Dillon*, 1:14-cv-13220; *Rice*, 1:14-cv-13257; *Lock*, 1:14-cv-13262; *Reed*, 1:14-cv-13265; *Wilfing*, 1:14-cv-13267; *Yoe*, 1:14-cv-13268; *Vitou*, 1:14-cv-13294; *Tirotta*, 1:14-cv-13296; *Smith*, 1:14-cv-13304; *Robinson*, 1:14-cv-13307; *Kaser*, 1:14-cv-13322; *Hinkle*, 1:14-cv-13323; *Miller*, 1:14-cv-13324; *Kubiszewski*, 1:14-cv-13325; *Jackson*, 1:14-cv-13327; *Roark*, 1:14-cv-13329; *Romano*, 1:14-cv-13332; *Walter*, 1:14-cv-13335; *Rulli*, 1:14-cv-13411; *Behrens*, 1:14-cv-13412; *Tuff*, 1:14-cv-13413; *Frain*, 1:14-cv-13414; *Fortier*, 1:14-cv-13415; *Mohr*, 1:14-cv-13483; *Sieczko*, 1:14-cv-13484; *Surowiec*, 1:14-cv-13486; *Troxel*, 1:14-cv-13488; *Trost*, 1:14-cv-13489; *Redman*, 1:14-cv-13493; *Ross*, 1:14-cv-13494; *Reinhardt*, 1:14-cv-13495; *Jackson*, 1:14-cv-13661; *Pinkstaff*, 1:14-cv-13719; and *Calvo-Nelson*, 1:14-cv-13734; *Lambert*, 1:13-cv-10351.

MDL No. 2419
Master Docket:
1:13-md-2419-
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LIBERTY INDUSTRIES, INC.'S REPLY IN OPPOSITION TO
PLAINTIFFS' STEERING COMMITTEE'S SUPPLEMENTAL RESPONSE TO ITS
MOTIONS FOR SUMMARY JUDGMENT

I. INTRODUCTION

Liberty Industries, Inc. (“Liberty”) hereby files its response to the Plaintiffs’ Steering Committee’s (“PSC”) Supplemental Response to Liberty’s Omnibus Motion for Summary Judgment in Cases Filed by Plaintiffs Injected in Indiana (“Supplemental Response”). The Supplemental Response is filed as a supplement to the PSC’s previously-filed Rule 56(d) response to Liberty’s motions for summary judgment (“Rule 56(d) Response”) [Dkt. Nos. 1518, 1519]. As set forth in Liberty’s motions for summary judgment [Dkt. Nos. 1471, 1472, Lambert Dkt. Nos. 29, 30], Liberty constructed certain portions of three cleanrooms for New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center (“NECC”) and/or Ameridose in 2005, 2006, and 2008 and was last on the site in 2008. It is being sued in this matter on the theory that the cleanrooms it built several years prior to the fungal meningitis outbreak in 2012 contained defects that caused the outbreak. There is no evidence to support these allegations.

As such, Liberty filed motions for summary judgment seeking judgment in its favor. As set forth in those motions, the undisputed facts establish that the contaminated methylprednisolone acetate (“MPA”) that led to the fungal meningitis outbreak was not compounded in the 2005 or the 2008 cleanrooms built by Liberty. With respect to the 2006 cleanroom built by Liberty, the undisputed facts also establish that that cleanroom was fully-functioning and complied with the standard set forth in the applicable contract between Liberty and NECC, ISO 14644-1, after construction and on June 22, 2012, just prior to the subject outbreak. In fact, the PSC conceded at the December 4th status conference with the Court that it does not know in which room the MPA was compounded. However, basic logic also fatally undermines the PSC’s allegations against Liberty. If Liberty breached a duty and therefore

provided a compromised cleanroom, then the natural, probable, and foreseeable result would be widespread contamination of all or substantially all drugs compounded in Liberty's cleanrooms, not just three random batches of MPA. Instead, there is evidence that non-contaminated MPA was compounded both before and after the batches of contaminated MPA. In sum, both the undisputed record and logic mandate the entrance of summary judgment in favor of Liberty.

Nevertheless, the PSC, in its Rule 56(d) Response and supplement thereto, requests that a ruling on Liberty's motions for summary judgment be deferred so that the PSC can conduct additional discovery. The PSC has not supplemented its earlier defective filings with any new affidavit or declaration that meets the requirements of the applicable rule. Kristen A. Johnson, who signed the Supplemental Response, carefully avoids submitting any document sworn to under the penalties of perjury. In addition, the PSC concedes that, despite being in possession of all of Liberty's documents regarding the cleanrooms it built for NECC and/or Ameridose since July 2013, it is unable to establish causation against Liberty. See Supplemental Response, p. 10; Affidavit of Nicole D. Dorman, Esq., attached as Exhibit A to Liberty's Reply to PSC's Rule 56(d) Response [Dkt. No. 1544], ¶¶ 2-4 ("Dorman Aff."). None of the additional discovery the PSC requests will assist it in carrying its burden of establishing causation in this matter. Accordingly, the PSC's Rule 56(d) Response and supplement thereto must be denied and summary judgment must enter in favor of Liberty now.

II. LEGAL ARGUMENT

A. The PSC's Rule 56(d) Response and Supplemental Response Fail to Meet the Basic Requirements of Rule 56(d).

Rule 56(d) requires that the party opposing summary judgment establish "by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition." Fed.R.Civ.P. 56(d). The PSC's initial Rule 56(d) Response failed to meet this standard because

it did not contain an adequate declaration or affidavit. It was supported by only the deficient declaration of Marc Lipton, the member of the PSC in charge of developing the case against Liberty. Mr. Lipton's declaration is deficient under Rule 56(d) because it merely recites the same allegations against Liberty contained in the Master Complaint and indicates that the PSC "needs additional discovery to investigate and/or prove" those allegations. See Declaration of Marc Lipton, ¶9 ("Lipton Dec."). It fails to set forth specified reasons, as required by Rule 56(d), as to why the PSC cannot present facts essential to justify an opposition to Liberty's summary judgment motions.

The PSC's Supplemental Response fails to cure this defect. It is accompanied by no declaration or affidavit. Further, while it was submitted by Ms. Johnson, on behalf of the PSC, Ms. Johnson does not set forth any basis for her authority to make the statements contained in the Supplemental Response. She is not the member of the PSC principally tasked with developing the case against Liberty; Mr. Lipton is. See Lipton Dec., ¶1. Further, she was not present during the key discovery events upon which the PSC's Supplemental Response is largely based, i.e. the depositions of Jeffrey Erickson and Robert Kaiser. Because the PSC has failed, both in its initial Rule 56(d) Response and the supplement thereto, to meet the most basic requirement of Rule 56(d) to provide an adequate affidavit or declaration, its request for additional discovery must be denied. See Boyle v. Barnstable Police Dept., 818 F.Supp. 2d 284, 299 (D. Mass. 2011) (denying request for additional discovery to oppose summary judgment because "[b]y its terms, the rule requires an affidavit or declaration").

B. The PSC Has Failed to Show How the Requested Discovery Will Affect the Outcome on Liberty's Motions for Summary Judgment.

The PSC's Supplemental Response sets forth a laundry-list of discovery that the PSC claims that it needs to oppose Liberty's motions for summary judgment. However, under Rule

56(d), the PSC is required to do more than merely set forth discovery that it would like to conduct. It is required to show “a plausible basis for believing that additional facts probably exist” and “an explanation of how those facts, if collected, will suffice to defeat the pending summary judgment motion.” See Rivera-Torres v. Rey-Hernandez, 502 F.3d 7, 10 (1st Cir. 2007); Nieves-Romero v. U.S., 715 F.3d 375, 381 (1st Cir. 2013), citing Velez v. Awning Windows, Inc., 375 F.3d 35, 40 (1st Cir. 2004). Accordingly, in order to be entitled to relief under Rule 56(d), the PSC must show that the additional discovery it requests will establish facts to support its claims against Liberty, i.e. that Liberty breached a duty with respect to the cleanrooms it built and that that breach caused the alleged harm to the plaintiffs. The PSC has not and cannot do so.

The PSC requests the following discovery:

- (1) depositions of Liberty’s owner and two former employees;
- (2) discovery from NECC; and
- (3) expert discovery.

There is no plausible basis to believe that any of the above-referenced discovery will establish facts to defeat Liberty’s motions for summary judgment.

1. There Is No Plausible Basis to Believe that Depositions of Liberty’s Owner and Its Former Employees Will Affect the Outcome on Liberty’s Motions for Summary Judgment.

The PSC seeks to take the depositions of the owner of Liberty, John Nappi, Jr., and two former employees of Liberty, George Pollick and Jay Schneider. The PSC claims that those depositions are necessary to address three topics: “the design of the 2005 cleanroom”; “the addition of the passthrough to the 2006 cleanroom”; and “the decision not to add a secondary ceiling to the 2006 cleanroom.” While the PSC claims the need to explore these topics, it has

failed to establish a single specified material fact that it is likely to glean from the depositions.

In addressing a similar request for additional depositions, the Court of Appeals for the First

Circuit affirmed the denial of Rule 56(d) relief, stating:

[t]he affidavit appellants presented in support of their motion for relief under Rule 56[(d)] did little more than list the witnesses appellants wished to depose, and allege ‘[t]hat because of the complexity of the case and the number of parties involved, the parties had not yet completed discovery.’ The affidavit presented no plausible basis for asserting a belief that ‘specified’ discoverable facts probably existed.

Mattoon v. City of Pittsfield, 980 F.2d 1, 7-8 (1st Cir. 1992). Because the PSC’s desire to take the depositions of Mr. Nappi, Mr. Pollick, and Mr. Schneider is unaccompanied by any explanation as to how those depositions will elicit specified material facts supporting a triable issue against Liberty, the Rule 56(d) Response must be denied. See Mowbray v. Waste Mgmt. Holdings, Inc., 45 F. Supp. 2d 132, 143 (D. Mass. 1999) (“[i]f all one had to do to obtain a grant of a Rule 56[(d)] motion were to allege possession by movant of certain information and other evidence, every summary judgment decision would have to be delayed while the non-movant goes fishing in the movant’s file”).

Further, the PSC has already been afforded ample discovery on each of the topics it wishes to explore in the depositions. It already knows the design of each of the cleanrooms built by Liberty based on the 9,921 pages of documents that were produced to the PSC on July 29, 2013. See Dorman Aff., ¶¶ 2-4. Those documents included design sketches for each cleanroom. It has also deposed two senior Liberty employees, including Mr. Erickson, Liberty’s Engineering Manager who was involved in the design stages for the 2006 and 2008 cleanrooms and the construction of all of the cleanrooms. No restriction or limitation was placed on the examination of those witnesses. In addition, there is also no dispute that the construction features that the PSC has identified as its proposed deposition topics for Mr. Nappi, Mr. Pollick, and Mr.

Schneider, i.e. the passthrough and the absence of a secondary ceiling, were features of the 2006 cleanroom built by Liberty. As these facts are undisputed, depositions of Liberty personnel regarding these features cannot and will not affect the outcome on Liberty's motions for summary judgment.

Instead, what the PSC needs to defeat summary judgment on its claims against Liberty is what it indisputably cannot prove, causation. That is, in order to support its claims against Liberty, the PSC must demonstrate that some act or omission of Liberty caused the subject outbreak. Depositions of Mr. Nappi, Mr. Pollick, and Mr. Schneider will not aid the PSC in this regard as they can offer no testimony regarding causation. The PSC appears to acknowledge this fact as it concedes later on in its Supplemental Response that "[e]xperts will be needed...for purposes of establishing causation." See Supplemental Response, p. 9. Having acknowledged that experts are required for the causation element of their claim, there is no basis to believe that deposing Mr. Nappi, Mr. Pollick, or Mr. Schneider will assist the PSC in defeating Liberty's summary judgment motions.

In short, if there was any valid basis to the PSC's claims that Liberty caused the subject fungal meningitis outbreak, then the PSC would be able to prove it by now. It has been in possession of all of Liberty's documents relating to the cleanrooms and has inspected the NECC facility. It has had more than ample time since coming into possession of those documents in July 2013 and conducting that inspection in December 2012 to retain experts to offer testimony regarding alleged defects in Liberty's design and construction of the cleanrooms and how those defects allegedly caused the subject fungal meningitis outbreak. Yet, the PSC has failed to produce such expert testimony. Its failure to do so only indicates what the record has already revealed, that the claims against Liberty have no basis. Claiming that depositions of Mr. Nappi,

Mr. Pollick, or Mr. Schneider will elicit facts to defeat Liberty's summary judgment motions is nothing short of a veiled attempt to delay summary judgment on an inevitably meritless claim.

2. There Is No Plausible Basis to Believe that Discovery from NECC Will Affect the Outcome on Liberty's Motions for Summary Judgment.¹

The PSC also claims that it needs discovery from NECC to oppose Liberty's summary judgment motions. In addition to the inability of this discovery, like the requested depositions of Mr. Nappi, Mr. Pollick, and Mr. Schneider, to establish the necessary, and indisputably missing, element of the plaintiffs' claims against Liberty, i.e. causation, this discovery will also not affect the outcome on Liberty's summary judgment motions for several other reasons.

First, the PSC claims that it needs discovery from NECC to "confirm" certain information provided by Liberty, namely that the contaminated MPA was compounded in the 2006 cleanroom, Liberty's representations to NECC about the intended use of the cleanrooms, and that NECC made significant modifications to the cleanrooms built by Liberty. The PSC is not entitled to delay a ruling on Liberty's summary judgment motions to merely "confirm" the evidence already on the record. The PSC has failed to show any plausible basis to believe that discovery from NECC would contradict the evidence already established on the record.

Accordingly, delaying a ruling on Liberty's motions for summary judgment to permit such discovery would run directly counter to the purpose of Rule 56(d). See Mattoon, 980 F.2d at 8, citing Paterson-Leitch Co. v. Mass. Mun. Wholesale Elec. Co., 840 F.2d 985, 988 (1st Cir. 1988) (Rule 56(d) request "should articulate some plausible basis for the party's belief that *specified* 'discoverable' material facts likely exist") (emphasis original).

¹ In addition to the PSC's failure to show any plausible basis that the requested discovery from NECC would establish facts to defeat Liberty's motions for summary judgment, as required by Rule 56(d), there is also serious doubt that the discovery could even be had. Given the recent criminal charges against one former NECC pharmacist and the potential for criminal charges against other NECC personnel, it is questionable that any discovery could be elicited from them without them seeking the protection of the Fifth Amendment.

In addition, the PSC also claims that it needs discovery from NECC “to prove what representations were exchanged between NECC and Liberty regarding the intended use of the cleanrooms.” Yet, the PSC has been in possession of the contracts between Liberty and NECC and/or Ameridose, in which Liberty’s obligations with respect to the cleanrooms are set forth, since July 2013. See Dorman Aff., ¶¶ 2-4. The PSC has also been in possession of all of Liberty’s documents, comprised of at least 9,921 pages and including correspondence between Liberty, NECC, Ameridose, and third parties, regarding the cleanrooms for the same amount of time. Id. The PSC has failed to show how any of those documents or any of the deposition testimony of Mr. Erickson or Mr. Kaiser establish a plausible basis to believe specified material facts regarding “representations... exchanged between NECC and Liberty regarding the intended use of the cleanrooms” likely exist. The PSC’s mere desire to conduct additional discovery, without a showing that such discovery is likely to create a triable issue, does not entitle it to Rule 56(d) relief. See Pina v. Children’s Place a/k/a The Children’s Place Retail Stores, Inc., 740 F.3d 785, 795 (1st Cir. 2014) (the plaintiff’s “asserted desire to ‘explore’ is perhaps more accurately characterized as a desire to ‘fish,’ and in either case, it falls well short of establishing entitlement to Rule 56(d) relief”); Mowbray, 45 F.Supp. 2d at 143, quoting Mattoon, 980 F.2d at 8 (“Rule 56[(d)] affidavit [that] merely conjectures that something might be discovered but provides no realistic basis for believing that further discovery would disclose evidence’ is insufficient to delay summary judgment”).

3. There Is No Basis to Delay a Ruling on Liberty’s Motions for Summary Judgment to Permit Expert Discovery.

The PSC also contends that a ruling on Liberty’s motions for summary judgment should be delayed because “[e]xperts will be needed...especially for the purposes of causation.” It claims that it needs expert discovery in the areas of:

- “proper design and construction for cleanrooms”
- “proper design and construction for USP <797> cleanrooms”
- “proper certification methods for cleanrooms”
- “whether bi-annual air testing of the NECC cleanrooms performed by Scientific Air Analysis was properly performed”
- “whether positive test results in bi-annual air testing performed by Scientific Air Analysis would be dispositive of the issue of whether the cleanroom was properly designed, built, and certified”
- “whether Liberty performed a proper engineering analysis of the NECC facility when designing and constructing its cleanrooms”
- “what designs would have been more appropriate for the NECC facility”; and
- “whether cleanrooms should have even been placed inside NECC’s warehouse.”

All of these topics pertain to the proper procedures for designing, constructing and certifying cleanrooms. None of them depend on the outcome of any of the fact discovery requested by the PSC. As such, there is absolutely no good cause for the PSC’s failure to have secured expert testimony on these issues earlier in the proceedings. See Rivera-Torres, 502 F.3d at 10 (party seeking relief under Rule 56(d) must establish “good cause for his inability to have discovered or marshalled the necessary facts earlier in the proceedings”).

If there was any possible merit to the PSC’s allegations that Liberty’s design or construction of the cleanrooms caused the subject outbreak, then the PSC should be able to, based on the some 9,921 pages of documents produced by Liberty, its own inspection of the NECC facility, and the testimony of Liberty’s senior employees, Mr. Erickson and Mr. Kaiser, to produce expert testimony supporting the same. Delaying a ruling on Liberty’s motions for

summary judgment based the PSC's "hopes" that the expert testimony it has yet to secure will be forthcoming would undermine the entire summary judgment procedure. See Mattoon, 980 F.2d at 8, n. 11 ("[a]lthough appellants assert that they were prejudiced by the lack of opportunity to conduct discovery relating to appellee's expert witnesses, the availability of the information needed to defeat summary judgment did not depend on appellants' ability to depose defendants' experts. Appellants were free to submit affidavits from their own experts as to the existence of an ongoing violation...yet none were forthcoming").

III. CONCLUSION

In summary, the PSC has failed to meet its burden under Rule 56(d). While at first glance it may appear, based on the laundry-list of discovery set forth by the PSC, that Liberty's summary judgment motions are premature, a closer examination of the record and the procedural history of this case leads to only one conclusion, that the PSC's allegations against Liberty were made without any basis in fact. Now, more than a year after making those allegations, the PSC is still in search of a basis for those claims. In light of this complete failure of proof, Liberty respectfully requests that the Court act swiftly and deny the PSC's Rule 56(d) Response and supplement thereto and grant summary judgment in favor of Liberty.

The Court's failure to rule expeditiously on this matter will have dire results. As Liberty, by and through its counsel, advised the Court at the December 4th status conference, it is party to a declaratory judgment action, Great American E&S Ins. Co. v. Liberty Industries, Inc., 3:14-cv-00499-VLB, brought by its insurer, Great American E&S Insurance Company ("Great American"), concerning Great American's coverage obligations to Liberty in this matter. A ruling adverse to Liberty on Great American's unopposed summary judgment motion in that coverage action is anticipated at or around the end of this month. Once that ruling is issued,

Liberty, a small closely-held company, will be unable to fund its defense and will be forced to file for bankruptcy protection. Both the PSC and the Chapter 11 Trustee of NECC are aware of these facts. As such, Liberty implores the Court to exercise sound judicial discretion and put an end to the baseless claims asserted against Liberty in this matter by denying the PSC's Rule 56(d) Response and entering summary judgment in favor of Liberty.

WHEREFORE, Liberty respectfully requests that the Court deny the PSC's Rule 56(d) Response and supplement thereto, and grant summary judgment in favor of Liberty.

REQUEST FOR ORAL ARGUMENT

Liberty respectfully requests that the Court schedule oral argument on this matter on or before December 23, 2014. Alternatively, if Court is unwilling or unable to schedule oral argument by that date, it requests that the Court issue an expeditious ruling on the papers in this matter, without oral argument.

Respectfully submitted,

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By its attorneys,

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Dated: December 12, 2014

CERTIFICATE OF SERVICE

Pursuant to Local Rules 5.2(b)(2) and 5.4 of the Local Rules of the United States District Court for the District of Massachusetts, I hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and that paper copies will be sent by first-class mail to those indicated as non-registered participants, if any, on December 12, 2014.

/s/ Peter G. Hermes
Peter G. Hermes

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